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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/940,235      | 08/27/2001  | Girish Sahni         | 07064-009002        | 5356             |

7590 09/12/2002

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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1652

DATE MAILED: 09/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/940,235

Applicant(s)

SAHNI ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 9, and 32, drawn to streptokinase proteins, classified in class 435, subclass 216.
- II. Claims 4-6 and 8, drawn to streptokinase polynucleotides and host cells, classified in class 435, subclass 252.3.
- III. Claims 7 and 10-30, drawn to methods of making streptokinase proteins, classified in class 435, subclass 216.
- IV. Claim 31, drawn to methods of using streptokinase proteins, classified in class 424, subclass 94.5.

These inventions are different, each from the other, for the following reasons:

The nucleic acids of Invention II are related to the protein of Invention I by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells, as recited in Claim 7. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The methods of Invention III are related to the proteins of Invention I as process of making and product made. The inventions are distinct if either or both of the following can be

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shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product claimed can be made in a materially different process of making that product (MPEP § 806.05(h)). In the instant case, the protein can also be made by synthetic peptide synthesis.

The methods of Invention IV are related to the proteins of Invention I as product and process of use. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be practiced with another materially different product or (2) that the product claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein can be used for production of an antibody or in assays for the identification of agonists and antagonists of the enzyme.

The methods of Invention III, for making streptokinases, are related to the DNA of Invention II as a product and process of using. The inventions are distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) that the product claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA can also be used for hybridization assays such as Northern blot, Southern blot, and in situ hybridization.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of Invention IV can neither use the DNA product of Invention II nor be used to make said product.

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Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods of Inventions III and IV are independent as they comprise different steps, utilize different products and produce different results.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Invention III, methods of preparing hybrid plasminogen activator proteins including:

- i. Claim 10: a SK fused to a FBD in which a polynucleotide containing an altered polynucleotide block is used.
- ii. Claim 13: a SK fused to a FBD wherein the FBD is fused at the NH<sub>2</sub>-terminal of the SK.
- iii. Claim 14: a SK fused to a FBD wherein the FBD is fused in frame at the C-terminal end of the SK.
- iv. Claim 15: a SK fused to a FBD wherein the FBD is fused at the C-terminal end of a truncated SK.
- v. Claim 16: a SK fused to FBDs wherein a FBD is fused at each end of SK.
- vi. Claim 18: a SK fused to a FBD wherein the FBD is fused to the SK via a flexible polypeptide linker.
- vii. Claim 19: a SK fused to a FBD wherein the FBD is fused to the SK via a rigid polypeptide linker.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for

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prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 7, 10-12, 17, 20-30 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 8:30-5 EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan L. Swope, Ph.D.

  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
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